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| | 0275739 | 1997-30-0565D1 |

**INFORMATION DISCLOSURE STATEMENT
BY APPLICANT**

Applicant: REFF *et al.*

Appln. No.: 09/292,053

Filing Date: April 14, 1999

Date: October 30, 2003 Page 1 of 4

Examiner: P. Huynh

Group Art Unit: 1644

U.S. PATENT DOCUMENTS

| Examiner's Initials* | | Document Number | Date MM/YYYY | Name (Family Name of First Inventor) | Class | Sub Class | Filing Date |
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| Pak | AR | 4,975,369 | 12/1990 | Beavers <i>et al.</i> | | | |
| | BR | 5,348,876 | 09/1994 | Michaelson <i>et al.</i> | | | |
| | CR | 5,543,144 | 08/1996 | Chang <i>et al.</i> | | | |
| | DR | 5,585,089 | 12/1996 | Queen <i>et al.</i> | | | |
| | ER | 5,648,260 | 07/1997 | Winter <i>et al.</i> | | | |
| | FR | 5,648,267 | 07/1997 | Reff | | | |
| | GR | 5,658,570 | 08/1997 | Newman <i>et al.</i> | | | |
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| | | | | | | ENCLOSED | NO |
| Pak | KR | WO 96/12741 | 05/1996 | WIPO | Glaxo Group Ltd. | | |
| | LR | WO 96/12742 | 05/1996 | WIPO | Glaxo Group Ltd. | | |
| | MR | WO 89/00138 | 01/1989 | WIPO | Gunnar Strömberg | | |
| | NR | WO 92/17207 | 10/1992 | WIPO | Tanox Biosystems Inc. | | |
| | OR | WO 93/02108 | 02/1993 | WIPO | IDEC Pharmaceuticals Inc. | | |
| | PR | WO 88/06891 | 09/1988 | WIPO | Aktiebolaget Astra | | |
| ✓ | QR | WO 87/07302 | 12/1987 | WIPO | Laboratoires Unicet | | |

OTHER

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| Pak | RR | Rector <i>et al.</i> , "Detection and characterization of monoclonal antibodies specific to IgE receptors on human lymphocytes by flow cytometry", <i>Immunol.</i> , 55: 481-488 (1985). |
| | SR | Suemura <i>et al.</i> , "Monoclonal anti-Fc epsilon receptor antibodies with different specificities and studies on the expression of Fc epsilon receptors on human B and T cells", <i>J. Immunol.</i> , 137: 1214-1220 (1986). |
| | TR | Noro <i>et al.</i> , "Monoclonal antibody (H107) inhibiting IgE binding to Fc epsilon R(+) human lymphocytes", <i>J. Immunol.</i> , 137: 1258-1263 (1986). |
| | UR | Yu <i>et al.</i> , "Negative feedback regulation of IgE synthesis by murine CD23", <i>Nature</i> 369: 753-756 (1994). |
| | VR | Bonnefoy <i>et al.</i> , "Regulation of IgE synthesis by CD23/CD21 interaction", <i>Int. Arch. Allergy Immunol.</i> , 107:40-42 (1995). |
| | WR | Grosjean <i>et al.</i> , "CD23/CD21 interaction is required for presentation of soluble protein antigen by lymphoblastoid B cell lines to specific CD4+ T cell clones", <i>Eur. J. Immunol.</i> , 24: 2982-2988 (1994). |
| | XR | Pene <i>et al.</i> , "Interleukin 5 enhances interleukin 4-induced IgE production by normal human B cells. The role of soluble CD23 antigen", <i>Eur J. Immunol.</i> , 18: 929-935 (1988). |
| | YR | Saxon <i>et al.</i> , "Soluble CD23 containing B cell supernatants induce IgE from peripheral blood B-lymphocytes and costimulate with interleukin-4 in induction of IgE", <i>J. Allergy Clin. Immunol.</i> , 86 (3 pt 1) 333-344 (1990). |
| ✓ | ZR | Hassner and Saxon, "Isotype-specific human suppressor T cells for IgE synthesis activated by IgE-anti-IgE immune complexes", <i>J. Immunol.</i> , 132: 2844 (1984). |

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| OCT 30 2003 | | Client Ref. No.: | Atty. Dkt. No.: | Examiner: | Group Art Unit: |
| | | 997-30-0565D1 | 037003-0275739 | P. Huynh | 1644 |
| Pk | AAR | Carr et al., "Mouse x human heterohybridomas as fusion partners with human B cell tumors", J. Immunol. Methods, 89: 61 (1986). | | | |
| | BBR | Boerner et al., "Production of antigen-specific human monoclonal antibodies from in vitro-primed human splenocytes", J. Immunol., 147: 86 (1991). | | | |
| | CCR | Luo et al., "Cross-linking of CD23 antigen by its natural ligand (IgE) or by anti-CD23 antibody prevents B lymphocyte proliferation and differentiation" J. Immunol., 146(7):2122-9 (1991). | | | |
| | DDR | Groves et al., "Production of an ovine monoclonal antibody to testosterone by an interspecies fusion", Hybridoma, vol. 6(1):71 (1987). | | | |
| | EER | Robbins, "Diseases of Immunity," Pathologic Basis of Disease, pp. 197-199 (1994). | | | |
| | FFR | Seaver, "Monoclonal Antibodies in Industry: More Difficult than Oringally Thought," Genetic Engineering, 14(14): 10 and 21 (1994). | | | |
| | GGR | Haak-Frendscho et al., "Administration of an anti-IgE antibody inhibits CD23 expression and IgE production in vivo", Immunology, 82:306 (1994). | | | |
| | HHR | Delespesse et al., "Human IgE-binding factors", Immunology Today, 10:159, (1989). | | | |
| | IIR | Durum and Oppenheim, "Proinflammatory Cytokines and Immunity," Fundamental Immunology, 3rd Edition, Chapter 21, p. 801-835, Raven Press Ltd. (1993). | | | |
| | JJR | Vercelli et al., "Induction of human IgE synthesis requires interleukin 4 and T/B cell interactions involving the T cell receptor/CD3 complex and MHC class II antigens", J. Exp. Med., 169:1295 (Apr. 1989). | | | |
| | KKR | Presta et al., "Humanization of an antibody directed against IgE", J. Immunology, 151(5):2623 (Sep. 1993). | | | |
| | LLR | Strike et al., "Production of human-human hybridomas secreting antibody to sheep erythrocytes after in vitro immunization", J. Immunol., 132(4): 1798 (Apr. 1984). | | | |
| | MMR | Cruse et al., Illustrated Dictionary of Immunology, CRC Press, p. 69 (1995). | | | |
| | NNR | Capon et al., "Designing CD4 immunoadhesins for AIDS therapy", Nature, 337:525 (Feb. 1989). | | | |
| | OOR | Bourget et al., Eur. J. Immunol., 12(7):1872-76 (1995). | | | |
| | PPR | Bonnefoy et al., "A new role for CD23 in inflammation", Immunol. Today, 17(9): 418-20 (1996). | | | |
| | QQR | Urlaub et al., Somatic Cell and Mol. Genetics, 12(6):555-66 (1986). | | | |
| | RRR | Co et al., "Humanized anti-Lewis Y antibodies: in vitro properties and pharmacokinetics in rhesus monkeys", Can. Res., 56:1118-25 (1996). | | | |
| | SSR | Ono et al., "Deletion of SHIP or SHP-1 reveals two distinct pathways for inhibitory signaling", Cell, 90:293-301 (1997). | | | |
| | TTR | Parren et al., "Characterization of IgG FcR-mediated proliferation of human T cells induced by mouse and human anti-CD3 monoclonal antibodies. Identification of a functional polymorphism to human IgG2 anti-CD3", J. Immunol., 148(3):695-701 (1992). | | | |
| | UUR | Steplewski et al., "Biological activity of human-mouse IgG1, IgG2, IgG3, and IgG4 chimeric monoclonal antibodies with antitumor specificity", Proc. Natl. Acad. Sci., 85(13):4852-4856 (1988). | | | |
| | VVR | Lund et al., "Human Fc gamma RI and Fc gamma RII interact with distinct but overlapping sites on human IgG", J. Immunol., 147(8):2657-2662 (1991). | | | |
| | WVR | Co et al., "Chimeric and humanized antibodies with specificity for the CD33 antigen", J. Immunol., 148(3):1149-1154 (1992). | | | |
| | XXR | Shakib et al., "A study of the interrelationship between circulating IgG subclass anti-IgE autoantibodies, IgE and soluble CD23 in asthma", Allergol. Immunopathol., 21(1):20-24 (1993). | | | |
| | YYR | Spiegelberg et al., "Fc receptors for IgE and interleukin-4 induced IgE and IgG4 secretion", J. Invest. Dermatol., 94(6):49S-52S (1990). | | | |
| | ZZR | Maliszewski et al., "Induction of B cell activities by interleukin 4 is inhibited by a receptor-specific monoclonal antibody in vitro", Eur. J. Immunol., 20:1735-1740 (1990). | | | |
| | AAAR | Yanagihara et al., "Suppression of IgE production by IPD-1151T (suplatast tosilate), a new dimethylsulfonium agent: (1). Regulation of murine IgE response", Jpn J. Pharmacol., 61:23-30 (1993). | | | |
| | BBBR | Hjultström et al., "No role of interleukin-4 in CD23/IgE-mediated enhancement of the murine antibody response in vivo", Eur. J. Immunol., 25:1469-1472 (1995). | | | |
| | CCCR | Escura et al., Immunol., 86:343-350 (1995). | | | |
| ✓ | DDDR | Gustavsson et al., "CD23/IgE-mediated regulation of the specific antibody response in vivo", J. Immunol., 152(10):4793-4800 (1994). | | | |

Dr. N. H.

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| | | 1997-30-0565D1 | 037003-0275739 | P. Huynh | 1644 |
| PJK | EEER | Yamagihara et al., "Establishment of a sensitive radioimmunoassay for the detection of human IgE-binding factor (soluble CD23)", Int. Arch. Allergy Immunol., 98:189-199 (1992). | | | |
| | FFFR | Bonnefoy et al., "Receptors for IgE", Curr. Opin in Immunol., 5:944-9 (1993). | | | |
| | GGGR | Burton et al., "Human antibody effector function", Adv. Immunol., 51:1-84 (1992). | | | |
| | HHHR | Paul et al., Fundamental Immunology, 705 & 870 (1994). | | | |
| | IIIR | Webster's II New Riverside University Dictionary, Houghton-Mifflin Co., Boston, p. 933 (1984). | | | |
| | JJJR | Van Noort et al., "Cell Biology of Autoimmune Diseases," Intl. Rev. of Cytology, 178:127-205 (1998). | | | |
| | KKKR | Abaza et al., "Effects of Amino Acid Substitutions Outside an Antigenic...", J. Prot. Chem., 11(5):433-444 (1992). | | | |
| | LLLL | Plater-Zyberk et al., "Marked amelioration of established collagen-induced arthritis by treatment with antibodies to CD23 in vivo", Nature Medicine, 1(8):781-785 (1995). | | | |
| | MMMR | Skolnick et al., "From genes to protein structure and function: novel applications of computational approaches in the genomic era", TIBTECH, 18:34-9 (2000). | | | |
| | NNNR | The Merck Manual of Diagnosis and Therapy, 17 th Edition, Beers et al., eds., Whitehouse Station, NJ, pp. 416-422 (1999). | | | |
| | OOOR | Busse et al., J. of allergy and Clinical Immunol., 107(2):abstract no. 354 (Feb. 2001). | | | |
| | PPPR | Nakamura et al., "In vitro IgE inhibition in B cells by anti-CD23 monoclonal antibodies is functionally dependent on the immunoglobulin Fc domain", Intl. J. of Immunopharmacol., 22:131-41 (2000). | | | |
| | QQQR | Yoshikawa et al., "Soluble Fc epsilon RII/CD23 in patients with autoimmune diseases and Epstein-Barr virus-related disorders: analysis by ELISA for soluble Fc epsilon RII/CD23", Immunomethods, 4(1):65-71 (Feb. 1994). | | | |
| | RRRR | Muino et al., "The importance of specific IgG and IgE autoantibodies to retinal S antigen, total serum IgE, and sCD23 levels in autoimmune and infectious uveitis", J. clin. Immunol., 19(4):215-222 (Jul. 1999). | | | |
| | SSSR | Soh et al., "IgE and its related phenomena in bullous pemphigoid", Br. J. Dermatol. 128(4):371-377 (Apr. 1993). | | | |
| | TTTR | Fries et al., "Monocyte receptors for the Fc portion of IgG studies with monomeric human IgG1: normal in vitro expression of Fc gamma receptors in HLA-B8/Drw3 subjects with defective Fc gamma-mediated in vivo clearance", J. Immunol., 129: 1041-1049 (1982). | | | |
| | UUUR | Kurlander and Batker et al., "The binding of human immunoglobulin G1 monomer and small, covalently cross-linked polymers of immunoglobulin G1 to human peripheral blood monocytes and polymorphonuclear leukocytes", J. Clin. Invest., 69: 1-8 (1982). | | | |
| | VVVR | Woof, "The monocyte binding domain(s) on human immunoglobulin G", Mol. Immunol., 21:523-527 (1984). | | | |
| | WWWR | Karas et al., "Characterization of the IgG-Fc receptor on human platelets", Blood, 60:1277-1282 (1982). | | | |
| | XXXR | Van de Winkel and Anderson, "Biology of human immunoglobulin G Fc receptors", J. Leuk. Biol., 49:511-524 (1991). | | | |
| | YYR | Huizinga et al., "Binding characteristics of dimeric IgG subclass complexes to human neutrophils", J. Immunol., 142:2359-2364 (1989). | | | |
| | ZZR | Bosma et al., "A severe combined immunodeficiency mutation in the mouse", Nature, 301:527 (1983). | | | |
| | AAAAR | Mosier et al., "Transfer of a functional human immune system to mice with severe combined immunodeficiency", Nature, 335:256 (1988). | | | |
| | BBBBR | Mosier et al., "Immunodeficient mice xenografted with human lymphoid cells: new models for in vivo studies of human immunobiology and infectious diseases", J Clin Immunol., 10:185-91 (1990). | | | |
| | CCCCR | Abedi et al., "Immunoglobulin production in severe combined immunodeficient (SCID) mice reconstituted with human peripheral blood mononuclear cells", Eur. J. Immunol., 22:823 (1992). | | | |
| ✓ | DDDDR | Mazingue et al., "Obtention of a human primary humoral response against schistosome protective antigens in severe combined immunodeficiency mice after the transfer of human peripheral blood mononuclear cells", Eur. J. Immunol., 21:1763 (1991). | | | |

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| OTHER (Continued) OCT 30 2003 | | Client Ref. No.: 997-30-0565D1 | Atty. Dkt. No.: 037003-0275739 | Examiner: P. Huynh | Group Art Unit: 1644 |
| PKH | AR | Kilchherr et al., "Regulation of human IgE response in hu-PBL-SCID mice", Cellular Immunology, 151:241 (1993). | | | |
| | BR | Spiegelberg et al., "Role of interleukin-4 in human immunoglobulin E formation in hu-PBL-SCID mice", J. Clin. Invest., 93:711 (1994). | | | |
| | CR | Carballido et al., "IL-4 induces human B cell maturation and IgE synthesis in SCID-hu mice. Inhibition of ongoing IgE production by in vivo treatment with an IL-4/IL-13 receptor antagonist", J. Immunol., 155:4162 (1995). | | | |
| | DR | King et al., "Expression, purification and characterization of a mouse-human chimeric antibody and chimeric Fab' fragment", Biochem J., 281:317-23 (1992). | | | |
| | ER | Queen et al., "A humanized antibody that binds to the interleukin 2 receptor", Proc. Nat. Acad. Sci. USA, 86:10029 (1989). | | | |
| | FR | Love et al., "Recombinant antibodies possessing novel effector functions", Methods Enzymol., 178:515-27 (1989). | | | |
| | GR | Hutzel et al., "Generation and characterization of a recombinant/chimeric B72.3 (human gamma 1)", Cancer Res., 51:181 (1991). | | | |
| | HR | Chiang et al., "Direct cDNA cloning of the rearranged immunoglobulin variable region", Biotechniques, 7(4):360-6 (1989). | | | |
| | IR | Heinrich et al., "Characterization of a human T cell-specific chimeric antibody (CD7) with human constant and mouse variable regions", J. Immunol., 143:3589 (1989). | | | |
| | JR | Hardman et al., "Generation of a recombinant mouse-human chimaeric monoclonal antibody directed against human carcinoembryonic antigen", Int. J. Cancer, 44:424 (1989). | | | |
| | KR | Orlandi et al., "Cloning immunoglobulin variable domains for expression by the polymerase chain reaction", Proc. Nat. Acad. Sci. USA, 86(10):3833-7 (1989). | | | |
| | LR | Norman et al., "Reversal of Acute Allograft Rejection With Monoclonal Antibody", Transpl. Proc., 17:39-41 (1985). | | | |
| | MR | Sarfati et al., "Elevation of IgE-binding factors in serum of patients with B cell-derived chronic lymphocytic leukemia", Blood, 71:94-98 (1988). | | | |
| ✓ | NR | Saragovi et al., "Design and synthesis of a mimetic from an antibody complementarity-determining region", Science, 262:53(5021):792-5 (1991). | | | |
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INFORMATION DISCLOSURE STATEMENT
BY APPLICANT

Applicant: Mitchell E. REFF et al.

Appl. No.: 09/292,053

Filing Date: April 14, 1999

Examiner: P. Huynh

Group Art Unit: 1644

Date: January 5, 2004

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| Examiner's Initials* | Document Number | Date MM/YYYY | Name (Family Name of First Inventor) | Class | Sub Class | Filing Date (if appropriate) |
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| PHH | ER | Ngo et al., "Computational Complexity, Protein Structure Prediction, and the Levinthal Paradox," 1994, <u>The Protein Folding Problem and Tertiary Structure Prediction</u> , Birkhauser Boston, pp. 490-495. |
| | FR | Boulet et al., "Inhibitory Effects of an Anti-IgE Antibody E25 on Allergen-Induced Early Asthmatic Response," <u>Am J Respir Crit Care Med</u> , (1997) 155:1835-44. |
| | GR | Casale et al., "Use of an anti-IgE humanized monoclonal antibody in ragweed-induced allergic rhinitis," <u>J Allergy Clin Immunol</u> , (1997), 100:110-120. |
| | HR | Coyle et al., "Central Role of Immunoglobulin (Ig) E in the Induction of Lung Eosinophil Infiltration and T Helper 2 Cell Cytokine Production: Inhibition by a Non-anaphylactogenic Anti-IgE Antibody," <u>J Exp Med</u> , (1996), 183:1303-1310. |
| | IR | Fahy et al., "The Effect of an Anti-IgE Monoclonal Antibody on the Early and Late-Phase Responses to Allergen Inhalation in Asthmatic Subjects," <u>Am J Respir Crit Care Med</u> , (1997), 155:1828-34. |
| | JR | Ohashi et al., "Immunotherapy Affects the Seasonal Increase in Specific IgE and Interleukin-4 in Serum of Patients with Seasonal Allergic Rhinitis," <u>Scand J Immunol</u> , (1997), 46(1):67-77. |
| | KR | Ohashi et al., "Serum levels of specific IgE, soluble interleukin-2 receptor, and soluble intercellular adhesion molecule-1 in seasonal allergic rhinitis," <u>Annals of Allergy, Asthma, and Immunol</u> , (1997), 79:213-220. |
| | LR | Ohashi et al., "Ten-Year Follow-Up Study of Allergen-Specific Immunoglobulin E and Immunoglobulin G4, Soluble Interleukin-2 Receptor, Interleukin-4, Soluble Intercellular Adhesion Molecule-1 and Soluble Vascular Cell Adhesion Molecule-1 in Serum of Patients on Immunotherapy for Perennial Allergic Rhinitis," <u>Scand J Immunol</u> , (1998), 47:167-178. |
| | MR | Peebles et al., "Ragweed-specific antibodies in bronchoalveolar lavage fluids and serum before and after segmental lung challenge: IgE and IgA associated with eosinophil degranulation," <u>J Allergy Clin Immunol</u> , (1998), 101:265-273. |
| | NR | Pullerits et al., "An intranasal glucocorticoid inhibits the increase of specific IgE initiated during birch pollen season," <u>J Allergy Clin Immunol</u> , (1997), 100:601-605. |
| | OR | Reff et al., "Depletion of B Cells In Vivo by a Chimeric Mouse Human Monoclonal Antibody to CD20," <u>Blood</u> , (1994), 83:435-445. |
| | PR | Ward E.S. and Ghetie V., "The effector functions of immunoglobulins: implications for therapy," 1995, <u>Therapeutic Immunology</u> , 2:77-94. |

Examiner

Date Considered:

*EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP § 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

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